UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

MOSAIC HEALTH INC., and CENTRAL VIRGINIA HEALTH SERVICES, INC., *individually and on behalf of all those similarly situated*,

Plaintiffs,

v.

SANOFI-AVENTIS U.S., LLC, ELI LILLY AND COMPANY, LILLY USA, LLC, NOVO NORDISK INC., and ASTRAZENECA PHARMACEUTICALS LP,

Defendants.

DECISION AND ORDER

6:21-CV-06507 EAW

INTRODUCTION

Plaintiffs Mosaic Health, Inc. ("Mosaic Health") and Central Virginia Health Services, Inc. ("CVHS") (collectively "Plaintiffs") allege that defendant pharmaceutical companies Sanofi-Aventis U.S. ("Sanofi"), Eli Lilly and Company and Lilly USA, LLC ("Eli Lilly"), Novo Nordisk Inc. ("Novo Nordisk"), and AstraZeneca Pharmaceuticals LP ("AstraZeneca") (collectively "Defendants") have violated state and federal antitrust laws by coordinating to rescind a long-standing discount for "safety-net" hospitals and clinics that treat patients who would otherwise be unable to obtain care. (Dkt. 41). The Court previously granted Defendants' motion to dismiss for failure to state a claim, concluding that Plaintiffs had not plausibly alleged parallel conduct. (Dkt. 71). Plaintiffs have now

moved for leave to file a second amended complaint. (Dkt. 72). For the reasons that follow, the Court denies Plaintiffs' motion.

BACKGROUND

I. Factual Background

The factual background of this case is set forth in detail in the Court's Decision and Order dated September 2, 2022 (Dkt. 71), familiarity with which is assumed for purposes of the instant Decision and Order. The Court summarizes the most salient facts and the new allegations set forth in the proposed second amended complaint below. As required at this stage of the litigation, the Court treats Plaintiffs' factual allegations as true.

In 1992, Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, created the "340B Drug Discount Program," which "require[s] discounts on outpatient drugs purchased by healthcare providers serving underserved populations." (Dkt. 41 at ¶ 21). "The net savings and revenue generated through access to 340B Drug Discounts [are] sometimes referred to as 340B Savings" and "340B Savings are often a critical component of covered entities' ability to provide healthcare services to patients." (*Id*. at ¶¶ 23-24). Mosaic Health, for example, uses 340B savings to "help fund sliding fee discounted medications for patients in need." (*Id*. at ¶ 25). "Since at least 1996, and in greater volumes since 2010, all drug companies participating in the 340B Drug Discount Program have offered Contract Pharmacy 340B Drug Discounts to covered entities. To do so, drug companies have offered covered entities the 340B Drug Discount on covered outpatient drugs purchased on the covered entities' own accounts but shipped to their registered Contract Pharmacy sites." (*Id*. at ¶ 55).

A typical arrangement involving a contract pharmacy would work as follows: (1) a covered entity's patient arrives at a contract pharmacy for a covered outpatient drug; (2) the contract pharmacy, "sometimes itself and sometimes working with a 340B vendor . . . reviews the pharmacy prescription to identify the patient's prescription as 340B eligible and to match it to a particular covered entity"; (3) the contract pharmacy fills the prescription with inventory from the purchasing account of the covered entity; (4) the contract pharmacy charges the patient for any required co-pay or fee, "adjusted downward as appropriate by any sliding-fee scale arrangement between the pharmacy and the covered entity"; (5) the contract pharmacy collects reimbursements from any third-parties such as private insurers or Medicare Part D; and (6) the contract pharmacy remits any amounts collected to the covered entity and the covered entity pays the contract pharmacy a dispensing fee. (*Id*. at ¶ 56).

"[D]iabetes medications make up a significant portion of 340B covered entities' outpatient prescriptions and 340B Drug Discounts. And three of the most significant diabetes medications are rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics." (*Id*. at ¶ 74). Defendants "dominate three of today's most lucrative markets for diabetes treatments: (i) rapid-acting analog insulins; (ii) long-acting analog insulins; and (iii) incretin mimetics. Defendants compete against each other, as horizontal competitors, in these markets." (*Id*. at ¶ 68). Sanofi, Eli Lilly, and Novo Nordisk compete in the sale of rapid-acting analog insulins and long-acting analog insulins. (*Id*. at ¶¶ 75-84). Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca compete in the sale of incretin mimetics.

(*Id*. at ¶¶ 85-90). These products collectively represent "hundreds of millions or billions of dollars in annual sales for each company." (*Id*. at ¶ 91).

In 2020, Defendants spent millions of dollars "collectively lobbying the federal government . . . to limit 340B Drug Discounts with respect to diabetes medicines." (*Id*. at ¶ 100). However, those efforts were largely unsuccessful. (*Id*. at ¶¶ 100-116). On July 24, 2020, then-President Donald Trump issued Executive Order 13937, which "addressed the use of insulin (as well as epinephrine) within the 340B Drug Discount Program," but was "extremely limited in scope." (*Id*. at ¶¶ 102-103). "Executive Order 13937 promised to have relatively little impact on the volume of 340B Drug Discounts for insulin medications[.]" (*Id*. at ¶ 104).

On July 24, 2020, AstraZeneca advised the United States Department of Health and Human Services ("HHS") that it intended to limit contract pharmacy 340B drug discounts. (*Id*. at ¶ 118). More particularly, AstraZeneca stated that beginning October 1, 2020, and for certain of its products, it would "recognize one contract pharmacy per covered entity for those covered entities that do not maintain an on-site dispensing pharmacy." (*Id*.).

On or about July 27, 2020, Sanofi informed all 340B Drug Discount Program covered entities that it would be implementing a new initiative that would "cut off all Contract Pharmacy 340B Drug Discounts, which had been in place for a decade, unless covered entities provided new consideration to Sanofi." (*Id*. at ¶ 120). "The newly required consideration was entry into a contract to provide sensitive prescription claims data to a Sanofi vendor through a software portal on commercially unreasonable terms." (*Id*.). Sanofi announced that its new policy would take effect on October 1, 2020. (*Id*.).

The proposed second amended complaint explains that the Sanofi vendor was Second Sight Solutions and that the software portal is called 340B ESP. (Dkt. 72-2 at ¶ 136).

On August 19, 2020, Eli Lilly advised HHS that effective September 1, 2020, it would discontinue voluntarily honoring requests for 340B contract pharmacies except "primarily" where a covered entity did not have an in-house pharmacy. (Dkt. 41 at ¶ 120). Eli Lilly also "added a special exception to permit Contract Pharmacies to pass along certain insulin products at cost," but "that exception was infeasible for covered entities and pharmacies, as it required the Contract Pharmacies to fill prescriptions without any fee whatsoever." (*Id*. at ¶ 122).

On December 1, 2020, Novo Nordisk advised HHS that "it would stop offering Contract Pharmacy 340B Drug Discounts to all hospital covered entities" effective January 1, 2021. (*Id*. at ¶ 124).

The proposed second amended complaint provides additional information regarding the impact of Defendants' changes in their policies regarding contract pharmacy 340B drug discounts, as well as describing subsequent policy changes made by Defendants. By letter dated February 2, 2021, Sanofi indicated that it was limiting its restrictions to "five covered entity types, effective March 1, 2021: consolidated health center programs, disproportionate share hospitals, critical access hospitals, rural referral centers, and sole community hospitals." (Dkt. 72-2 at ¶ 141). On December 16, 2021, Eli Lilly announced "that it was adopting Sanofi's approach of 'utilizing the 340B ESP Second Sight Solutions platform' to 'permit 340B purchases' by covered entities for drugs shipped to Contract Pharmacies with Contract Pharmacy 340B Drug Discounts if 'the covered entity agrees to

provide, and does provide on an ongoing basis, claims-level data associated with such contract pharmacy orders' through the 340B ESP platform." (*Id*. at ¶ 142). On January 24, 2022, Novo Nordisk "announced that it would modify its policy regarding bill-to/ship-to distribution of 340B product to a contract pharmacy such that if a hospital covered entity does not have wholly owned contract pharmacies, that covered entity will be permitted to designate a total of two contract pharmacy locations—one retail pharmacy, and one specialty pharmacy (as determined by Novo Nordisk)—to which product purchased by the covered entity may be shipped." (*Id*. (internal quotation marks omitted)).

Sanofi's new policy caused "an immediate decrease in Contract Pharmacy 340B Drug Discount sales of more than 86% by units and by more than 90% by savings"; Eli Lilly's new policy led to the loss of 89% of sales by unit and almost 95% of prior savings; Novo Nordisk's new policy led to a decline of nearly 70% in savings and a decline of 64% in sales by units; and AstraZeneca's new policy led to a decline of over 85% in savings and a decline of over 90% in sales by units. (*Id*. at ¶¶ 182, 199, 218, 230). In other words, "the immediate impact of Defendants' restrictions was a decline of 60%-90% of [340B] sales by units or 70-95% as measured by lost 340B Savings." (*Id*. at ¶ 275).

II. Procedural Background

Mosaic Health commenced this putative class action on July 30, 2021. (Dkt. 1). The first amended complaint, which added CVHS as a plaintiff, was filed on October 22, 2021. (Dkt. 41). Defendants filed their joint motion to dismiss the first amended complaint on November 12, 2021. (Dkt. 47; Dkt. 48). On September 2, 2022, the Court granted Defendants' motion, but conditionally granted Plaintiffs leave to amend, contingent on

Plaintiffs filing a procedurally proper motion for leave to amend including a viable proposed second amended complaint. (Dkt. 71). Plaintiffs filed the instant motion for leave to amend on October 3, 2022. (Dkt. 72). Defendants filed their response on October 27, 2022 (Dkt. 74), and Plaintiffs filed their reply on November 3, 2022 (Dkt. 75). On February 2, 2023, Defendants filed a notice of supplemental authority. (Dkt. 76). The Court heard oral argument on July 20, 2023, and reserved decision. (Dkt. 78).

DISCUSSION

I. Legal Standard

Federal Rule of Civil Procedure 15 provides that the Court "should freely give leave [to amend] when justice so requires." Nevertheless, "it is within the sound discretion of the district court to grant or deny leave to amend." *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007). "A district court has discretion to deny leave for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party." *Id.* "[A] request to replead should be denied in the event that amendment would be futile." *Absolute Activist Value Master Fund Ltd. v. Ficeto*, 677 F.3d 60, 71 (2d Cir. 2012). "An amendment to a pleading is futile if the proposed claim could not withstand a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6)." *Lucente v. Int'l Bus. Machines Corp.*, 310 F.3d 243, 258 (2d Cir. 2002) (citation omitted).

"In considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), a district court may consider the facts alleged in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint." *DiFolco v. MSNBC Cable L.L.C.*, 622 F.3d 104, 111 (2d Cir. 2010). A court

should consider the motion by "accepting all factual allegations as true and drawing all reasonable inferences in favor of the plaintiff." *Trs. of Upstate N.Y. Eng'rs Pension Fund v. Ivy Asset Mgmt.*, 843 F.3d 561, 566 (2d Cir. 2016). To withstand dismissal, a claimant must set forth "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Turkmen v. Ashcroft*, 589 F.3d 542, 546 (2d Cir. 2009) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

"While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (internal quotations and citations omitted). "To state a plausible claim, the complaint's '[f]actual allegations must be enough to raise a right to relief above the speculative level.'" *Nielsen v. AECOM Tech. Corp.*, 762 F.3d 214, 218 (2d Cir. 2014) (quoting *Twombly*, 550 U.S. at 555).

II. Plaintiffs' Proposed Second Amended Complaint

The proposed second amended complaint sets forth the following claims: (1) violations of § 1 of the Sherman Act, 15 U.S.C. § 1; (2) "unreasonable restraint of trade" in violation of the laws of Arizona, California, Connecticut, the District of Columbia, Illinois, Florida, Iowa, Kansas, Maine, Maryland, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North

Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, West Virginia, and Wisconsin; and (3) unjust enrichment under the laws of Arizona, Hawaii, Illinois, Iowa, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, Oregon, Rhode Island, South Dakota, Utah, Vermont, Virginia, West Virginia, and Wisconsin. (Dkt. 72-2 at ¶¶ 370-480). Plaintiffs seek both damages and injunctive relief with respect to their Sherman Act claim. (*Id*. at ¶¶ 377-80).

Defendants oppose Plaintiffs' motion for leave to amend on the basis of futility, arguing that: (1) Plaintiffs have not remedied the defects the Court identified in their parallel conduct allegations; (2) the proposed second amended complaint does not allege the "plus factors" required to support an inference of conspiracy; (3) Plaintiffs' federal damages claims are barred by *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), because they are indirect purchasers of Defendants' drugs; (4) Plaintiffs' claims are an improper attempt to bring a private action to enforce the 340B statute, in contravention of *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011); (5) Plaintiffs' state law antitrust claims fail for the same reasons as their Sherman Act § 1 claim; and (6) Plaintiffs' state law unjust enrichment claims fall with the antitrust claims, are inadequately pleaded, and are futile for other, state-specific reasons. (Dkt. 74 at 11-31).[1] For the reasons that follow, the Court agrees that the proposed second amended complaint, like the first amended complaint, has

[1] The Court notes that "the *Illinois Brick* doctrine is not jurisdictional," *Mayor & City Council of Baltimore v. AbbVie Inc.*, 42 F.4th 709, 710 (7th Cir. 2022), and that it accordingly is not constrained to reach this issue first.

not sufficiently alleged parallel conduct. The Court further finds that Plaintiffs have not pleaded facts from which a factfinder could plausibly infer a conspiracy. Finally, the Court concludes that these defects also render the proposed amendments to Plaintiffs' state law claims futile.[2]

A. Sherman Act § 1 Claim

"Liability under § 1 of the Sherman Act, 15 U.S.C. § 1, requires a 'contract, combination . . ., or conspiracy, in restraint of trade or commerce.'" *Twombly*, 550 U.S. at 548 (quoting 15 U.S.C. § 1). "Because § 1 of the Sherman Act does not prohibit [all] unreasonable restraints of trade . . . but only restraints effected by a contract, combination, or conspiracy, [t]he crucial question is whether the challenged anticompetitive conduct stem[s] from independent decision or from an agreement, tacit or express." *Id.* at 553 (alterations in original) (quotations and citation omitted). "[S]tating such a claim requires a complaint with enough factual matter (taken as true) to suggest that an agreement was made." *Id.* at 556.

"The ultimate existence of an 'agreement' under antitrust law . . . is a legal conclusion, not a factual allegation." *Mayor and City Council of Balt., Md. v. Citigroup, Inc.*, 709 F.3d 129, 135-36 (2d Cir. 2013). "[A] plaintiff may . . . assert direct evidence that the defendants entered into an agreement in violation of the antitrust laws." *Id.* at 136.

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[2] The Court also has serious doubts about the viability of this matter in light of the Supreme Court's decision in *Astra USA*. Defendants have persuasively argued that this litigation is a backdoor attempt to use the antitrust laws to enforce Plaintiffs' preferred interpretation of the 340B statute. However, because the proposed second amended complaint fails to state an antitrust claim under well-established pleading standards, the Court need not reach this novel legal issue.

"[A] complaint may, alternatively, present circumstantial facts supporting the *inference* that a conspiracy existed." *Id.* (emphasis in original). "[A] horizontal agreement . . . may be inferred on the basis of conscious parallelism, when such interdependent conduct is accompanied by circumstantial evidence and plus factors." *Id.* (quotation omitted). "These 'plus factors' may include: a common motive to conspire, evidence that shows that the parallel acts were against the apparent individual economic self-interest of the alleged conspirators, and evidence of a high level of interfirm communications." *Id.* (quotation and footnote omitted).

"Without more, parallel conduct does not suggest conspiracy, and a conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality." *Twombly*, 550 U.S. at 556-57. In other words, allegations of parallel action "must be placed in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action." *Id.* at 557. "[W]ithout that further circumstance pointing toward a meeting of the minds, an account of a defendant's commercial efforts stays in neutral territory." *Id.* As the Second Circuit has explained:

> Examples of parallel conduct allegations that might be sufficient under *Twombly*'s standard include "parallel behavior that would probably not result from chance, coincidence, independent responses to common stimuli, or mere interdependence unaided by an advance understanding among the parties," and "complex and historically unprecedented changes in pricing structure made at the very same time by multiple competitors, and made for no other discernible reason."

Citigroup, 709 F.3d at 137 (quoting *Twombly*, 550 U.S. at 556 n.4 (quotation omitted)).

1. Failure to Allege Parallel Conduct

"'Parallel conduct' refers to the same or substantially similar actions taken by actors on the same level." *North Am. Soccer League, LLC v. U.S. Soccer Fed., Inc.*, 296 F. Supp. 3d 442, 460 n.26 (E.D.N.Y. 2017), *aff'd*, 883 F.3d 32 (2d Cir. 2018); *see also In re Amazon.com, Inc. eBook Antitrust Litig.*, No. 21-CV-00351 GHW VF, 2022 WL 4581903, at *11 (S.D.N.Y. Aug. 3, 2022) ("Under *Twombly*, parallel conduct, such as competitors adopting similar policies around the same time in response to similar market conditions, may constitute circumstantial evidence of anticompetitive behavior." (citation omitted)), *adopted*, 2022 WL 4586209 (S.D.N.Y. Sept. 29, 2022).

"Plaintiffs are not required to plead parallel conduct that is simultaneous or identical." *In re Farm-Raised Salmon and Salmon Products Antitrust Litigation*, No. 19-21551-CIV, 2021 WL 1109128, at *13 n.23 (S.D. Fla. Mar. 23, 2021); *see also In re Domestic Airline Travel Antitrust Litig.*, 221 F. Supp. 3d 46, 69 (D.D.C. 2016) ("Plaintiffs do not need to demonstrate that Defendants cut or limited capacity in exactly the same way in order to adequately allege parallel conduct."). However, where the alleged conspirators engaged in divergent conduct at significantly different times, a plaintiff's "allegations fall far short of demonstrating parallel behavior[.]" *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 228 (3d Cir. 2011); *see also LLM Bar Exam, LLC v. Barbri, Inc.*, 271 F. Supp. 3d 547, 579 (S.D.N.Y. 2017) (finding the plaintiff had not "established even . . . [the] basic building block" of parallel conduct where "[t]he First Amended Complaint [made] plain that [the defendant] schools banned [the plaintiff] from marketing on their campuses at different times over the span of several years"), *aff'd*, 922 F.3d 136 (2d Cir. 2019).

The Court previously determined that Plaintiffs had not adequately alleged parallel conduct, because "Plaintiffs' own allegations make clear that Defendants adopted four distinct policies regarding contract pharmacies and 340B drug discounts over the course of several months in mid-to-late 2020" and Plaintiffs had not "plausibly alleged that Defendants' disparate conduct ultimately achieved the same or a substantially similar end result." (Dkt. 71 at 11, 15). Plaintiffs argue that the proposed second amended complaint cures this deficiency because it "richly details the common impact of each Defendant's policy, showing that each policy led to the immediate decrease of sales through the Contract Pharmacy 340B Drug Discount channel by 60-90% in volume and 70-95% in lost 340B Savings" and "further details how Defendants implemented common policies . . . and why their various exceptions were so marginal that their policies accomplished the same results." (Dkt. 72-3 at 18).

The Court is unpersuaded by these arguments. Far from demonstrating that Defendants engaged in similar conduct, the second amended complaint's additional allegations provide further confirmation that the policies adopted by Defendants had substantial variations in both their timing and their particulars. To briefly summarize, the first defendant to make a change to its 340B contract pharmacy drug discount policy was Eli Lilly, which advised HHS in May of 2020 that it was ceasing to offer contract pharmacy discounts on one of its products, the drug Cialis. (Dkt. 72-1 at ¶ 139). Two months later, on July 24, 2020—immediately after Defendants' collective lobbying efforts to restrict 340B drug discounts failed—AstraZeneca advised HHS that beginning October 1, 2020, it would "recognize one contract pharmacy per covered entity for those covered entities that

do not maintain an on-site dispensing pharmacy" with respect to a subset of its products. (*Id*. at ¶ 134).

On July 27, 2020—again, in the immediate aftermath of the failure of Defendants' collective lobbying efforts—Sanofi announced a new policy regarding 340B contract pharmacy discounts, completely different from the policy adopted by AstraZeneca. (*Id*. at ¶ 136). Specifically, Sanofi announced that as of October 1, 2020,[3] it would begin requiring covered entities to "provide sensitive prescription claims data to a Sanofi vendor, Second Sight Solutions, through a software portal called 340B ESP on commercially unreasonable terms[.]" (*Id*.). Covered entities that refused to do so would no longer be eligible for 340B contract pharmacy discounts. (*Id*.).

Eli Lilly informed HHS of a further change to its policy on August 19, 2020, indicating that effective September 1, 2020, it would discontinue voluntarily honoring requests for 340B contract pharmacies except "primarily" where a covered entity did not have an in-house pharmacy, and with a special exception allowing contract pharmacies to pass along certain insulin products at cost. (*Id*. at ¶ 137-38). Novo Nordisk did not announce any changes to its 340B contract pharmacy discount policy until months later, on December 1, 2020, when it informed HHS that it would stop offering contract pharmacy 340B drug discounts to hospital covered entities—which notably does not include either of Plaintiffs—effective January 1, 2021. (*Id*. at ¶ 140).

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[3] Plaintiffs make much of the fact that both AstraZeneca's and Sanofi's policies were effective October 1, 2020. (*See* Dkt. 72-1 at ¶¶ 135-36). However, October 1, 2020, was the beginning of the next fiscal quarter.

Defendants have continued to make disparate changes to their policies over time. On February 2, 2021, Sanofi advised HHS that effective March 1, 2021, it would limit its restrictions to just five covered entity types—consolidated health center programs, disproportionate share hospitals, critical access hospitals, rural referral centers, and sole community hospitals. (*Id*. at ¶ 141). On December 16, 2021—more than a year after Sanofi first adopted the Second Sight Solutions platform—Eli Lilly announced that it too would "permit 340B purchases by covered entities for drugs shipped to Contract Pharmacies with Contract Pharmacy 340B Drug Discounts if the covered entity agrees to provide, and does provide on an ongoing basis, claims-level data associated with such contract pharmacy orders through the 340B ESP platform." (*Id*. at ¶ 142 (internal quotation marks omitted)). Further, on January 24, 2022, Novo Nordisk announced that it would allow hospital covered entities without wholly owned pharmacies to designate two contract pharmacies—one retail pharmacy and one specialty pharmacy. (*Id*.).

There is no question that beginning in 2020, Defendants have implemented restrictions on the use of contract pharmacies to make 340B purchases. However, Defendants' distinct and evolving policies, which have been adopted and updated over multiple years, simply do not amount to parallel conduct, for essentially the reasons discussed by the Court in its original Decision and Order. The new information added in the proposed second amended complaint is fully consistent with this conclusion. In particular, the fact that Eli Lilly, after first adopting its own unique policy in May and August of 2020, changed course in December of 2021 to adopt the Second Sight Solutions platform as Sanofi had done more than a year earlier is clear evidence of the individualized

nature of Defendants' actions. In other words, if Defendants' policies were functionally equivalent—as Plaintiffs contend—there would be no logical reason for Eli Lilly to have made this change.

Plaintiffs try to gloss over the significant differences in Defendants' behavior by contending that their disparate policies have had the "common effect of ending the vast majority of Contract Pharmacy 340B Drug Discounts for their drugs." (Dkt. 72-1 at 56). However, the data cited by Plaintiffs shows significant variation in the reduction of 340B drug sales. Specifically, Plaintiffs allege that Novo Nordisk's volume of drugs sold at 340B discount prices dropped approximately 60% the month after it adopted its new policy, while the other three defendants saw volume decreases of approximately 90%. (*See id*. at ¶¶ 182, 199, 218, 230). This dramatic difference between Novo Nordisk and the other three defendants underscores the differences in their allegedly parallel conduct.

Moreover, and as Defendants correctly point out, the data relied upon by Plaintiffs represents the decrease in 340B drug sales for all of Defendants' products, not just for the diabetes treatments that were allegedly the subject of the anticompetitive conspiracy. The Court agrees with Defendants that "[i]f anything, this multi-drug data undermines Plaintiffs' premise that Defendants were only willing to act in the diabetes-treatment markets where they supposedly moved together." (Dkt. 74 at 15).

In sum, the proposed second amended complaint, like the first amended complaint, fails to plausibly allege that Defendants engaged in parallel conduct. Because this is a necessary element of a claim under Sherman Act § 1, Plaintiffs' request for leave to amend their federal antitrust claim is futile.

2. Failure to Raise an Inference of Conspiracy

Assuming *arguendo* that Defendants' adoption of four substantially different policies regarding 340B contract pharmacy discounts over a period of either seven months (from May 2020 to December 2020) or a year and a half (if taking into account subsequent policy modifications made in 2021 and 2022) did constitute parallel conduct, Plaintiffs still must "allege enough facts to support the inference that a conspiracy actually existed." *Citigroup*, 709 F.3d at 136; *see also Twombly*, 550 U.S. at 556-57 ("when allegations of parallel conduct are set out in order to make a § 1 claim, they must be placed in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action"). "Post-*Twombly* courts have analyzed § 1 claims based on parallel conduct by horizontal competitors by inquiring whether 'plus factors' and/or other circumstantial evidence are present that, along with the parallel conduct, make it plausible to infer an agreement among competitors." *In re Int. Rate Swaps Antitrust Litig*., 261 F. Supp. 3d 430, 462-63 (S.D.N.Y. 2017). "An inference of conspiracy will not arise when the alleged conspirators' conduct made perfect business sense, or where there are obvious alternative explanations for the facts alleged." *Litovich v. Bank of Am. Corp*., 568 F. Supp. 3d 398, 417 (S.D.N.Y. 2021) (quotations and citations omitted); *see also Cenedella v. Metro. Museum of Art*, 348 F. Supp. 3d 346, 358 (S.D.N.Y. 2018) ("[A] plaintiff's complaint can be dismissed where there is an obvious alternative explanation to the facts underlying the alleged conspiracy among the defendants.").

Here, the allegations of the proposed second amended complaint set forth an obvious alternative explanation for the facts underlying the alleged conspiracy: the failure

of the Defendants' joint lobbying efforts. *See In re Treasury Securities Auction Antitrust Litigation*, No. 22-943, Slip Op. at 58 (2d Cir. Feb. 1, 2024) ("It is decidedly not indicative of a conspiracy that a group of similarly situated market participants would object, individually and separately, to a significant market development that could cut into their profits[.]"). Plaintiffs do not contest the legality of those joint lobbying efforts, which they concede were "long-running" and had cost Defendants millions of dollars. (Dkt. 72-1 at ¶¶ 6, 125). Moreover, the proposed second amended complaint acknowledges that the 340B program requires Defendants to sell their products at significantly discounted prices. (*Id*. at ¶ 37). It makes perfectly rational business sense for Defendants, who apparently viewed 340B drug discounts as a significant enough issue to spend millions of dollars lobbying the government for changes to the program, to have independently reacted to the failure of those lobbying efforts. *See, e.g., LaFlamme v. Societe Air France*, 702 F. Supp. 2d 136, 152 (E.D.N.Y. 2010) (finding no plausible inference of conspiracy where there was "an obvious potential stimuli and discernible reason aside from collusion that plausibly could have instigated independent decisions by defendants to impose surcharges" (quotations omitted)).

Plaintiffs' arguments to the contrary are unpersuasive. Plaintiffs contend that Defendants' "proffered theories nowhere account for why these four Defendants imposed their novel restrictions when a thousand others did not." (Dkt. 75 at 9). However, the proposed second amended complaint alleges that other drug manufactures made changes to their 340B contract pharmacy drug discount policies during the relevant time frame. For example, "two top drug manufacturers—Merck and Novartis—asked covered entities to

participate in the same software program mandated by Sanofi." (Dkt. 72-1 at ¶ 159). While Plaintiffs go on to allege that "unlike Sanofi, neither Merck nor Novartis cut off Contract Pharmacy 340B Drug Discounts for covered entities unwilling to participate" (*id*.), that does not change the fact that Merck and Novartis adopted new policies following the issuance of Executive Order 13937. Plaintiffs further acknowledge in the proposed second amended complaint that other drug manufacturers adopted policies similar to those adopted by Defendants in 2021 and 2022. (*Id*. at 160). The adoption of such policies by additional drug manufacturers further confirms that such policies make perfect business sense.

Plaintiffs suggest in the second amended complaint that it "would have been against any single Defendant's unilateral self-interest" to adopt the challenged policies because such action would "risk market share," in part by opening that single defendant up to severe regulatory sanctions. (Dkt. 72-1 at ¶ 278). However, these arguments cannot bear up under scrutiny. Initially, Plaintiffs' market share theory fails entirely to explain why only Novo Nordisk limited its restrictions to hospital covered entities, thus "leaving the entire non-hospital segment for Novo [Nordisk] to claim." (Dkt. 74 at 20). If Defendants were motivated by market share concerns as alleged by Plaintiffs, it would be irrational to leave a substantial market segment entirely to one co-conspirator.

Moreover, and as Defendants point out in opposition to Plaintiffs' motion for leave to amend (*see id*. at 19-20), Plaintiffs have not offered a plausible explanation for why Defendants would be economically incentivized to monopolize the 340B program market, when that market is defined by selling products at significantly discounted rates. Plaintiffs speculate that "[i]f hospitals and clinics end up preferring a drug because it has a Contract

Pharmacy 340B Drug Discount, that preference is most likely to be reflected in prescribing and administration patterns" outside of the 340B program. (Dkt. 72-1 at ¶ 70). However, that assertion is unsupported by any factual allegations. Accordingly, Plaintiffs' follow-up conclusion that "[t]he risk to a drug company's market share in restricting Contract Pharmacy 340B Drug Discounts is thus much larger than simply the loss of the potential sales to 340B eligible patients at Contract Pharmacies" (*id*. at ¶ 71) lacks plausibility.

With respect to the issue of regulatory sanctions, Plaintiffs make a "safety in numbers" argument that is unsupported by the factual allegations in the proposed second amended complaint. According to Plaintiffs, "[n]o rational manufacturer would risk acting alone to limit the sale of Contract Pharmacy 340B Drug Discounts because the United States has maintained that any such limitation violates Section 340B" and "[t]he Government could feasibly restrict a single manufacturer from federal healthcare programs without unduly undermining the mission of those federal healthcare programs in delivering critical medications to others because the exclusion of one manufacturer would not disrupt the availability of drugs of that manufacturer's competitors." (Dkt. 72-1 at ¶ 76). However, "if a manufacturer of critical medications, such as diabetes medications, conspired with all of the competing manufacturers of such medications, the Government could not feasibly restrict that group of manufacturers from federal healthcare programs." (*Id*. at ¶ 77).

The proposed second amended complaint undercuts this argument in multiple ways. First, contrary to Plaintiffs' argument that "[n]o rational manufacturer would risk acting alone to limit the sale of Contract Pharmacy 340B Drug Discounts because the United States has maintained that any such limitation violates Section 340B" (*id*. at ¶ 76), Eli Lilly

did just that in May of 2020 when it announced that it was ceasing to offer 340B contract pharmacy drug discounts on Cialis (*id*. at ¶ 139). Plaintiffs do not allege that Eli Lilly acted in coordination with any other drug manufacturer in making this announcement, nor do they allege that this action did not put Eli Lilly at risk of severe regulatory sanctions. Eli Lilly's unilateral restriction of contract pharmacy 340B drug discounts in May of 2020—before the alleged conspiracy is purported to have begun—directly contradicts Plaintiffs' "safety in numbers" theory.

Second, while Plaintiffs allege that Defendants' new policies "were imposed despite warnings by regulators that such restrictions were illegal" (Dkt. 72-1 at ¶ 165), the earliest "warning" they cite was issued on September 2, 2020 (*id*. at ¶ 166)—*after* Eli Lilly, AstraZeneca, and Sanofi had announced and implemented the policies at issue here. It is implausible that warnings issued *after* the challenged conduct began were an impetus for concerted action.

Nor do the other allegations in the proposed second amended complaint, viewed as a whole, plausibly give rise to an inference of conspiracy. While Plaintiffs' allegations that Defendants shared a common lobbyist and participated in the trade group PhRMA are indicative of an opportunity to conspire, they do not give rise to an inference of conspiracy without something more. *See PharmacyChecker.com, LLC v. Nat'l Ass'n of Boards of Pharmacy*, 530 F. Supp. 3d 301, 336 (S.D.N.Y. 2021). And while Plaintiffs allege that Defendants have been alleged to have engaged in antitrust conspiracies and price manipulation related to diabetes medication in the past (*see* Dkt. 72-1 at ¶¶ 331-36), they

have not tied those past allegations of wrongdoing to the conspiracy alleged in the instant action.

In sum, the Court finds that the proposed second amended complaint fails to set forth a viable claim under § 1 of the Sherman Act, both because it does not plausibly allege parallel conduct and because it does not otherwise plausibly allege conduct giving rise to an inference of conspiracy.

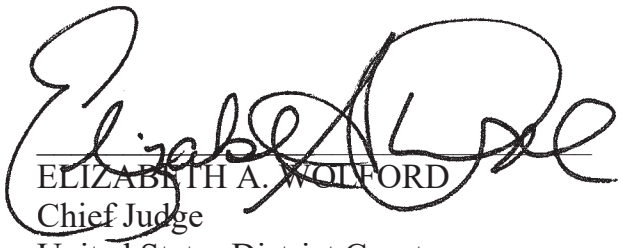
B. Proposed State Law Claim Amendments

The Court further finds that the proposed second amended complaint does not plausibly allege either state law antitrust claims or state law unjust enrichment claims. Both the proposed state law antitrust claims and the proposed state law unjust enrichment claims are premised on the allegation that Defendants have unlawfully conspired to overcharge Plaintiffs for their products. (*See* Dkt. 72-1 at ¶¶ 382-385, 389). However, the Court has determined for the reasons discussed at length above that Plaintiffs have not plausibly alleged that Defendants engaged in such a conspiracy. As such, their proposed amendments to their state law claims are futile.

CONCLUSION

For the foregoing reasons, Plaintiffs' motion for leave to file a second amended complaint (Dkt. 72) is denied. The Court having previously dismissed the first amended complaint (*see* Dkt. 71), the Clerk of Court is directed to close this case.

SO ORDERED.



ELIZABETH A. WOLFORD
Chief Judge
United States District Court

Dated: February 1, 2024
Rochester, New York